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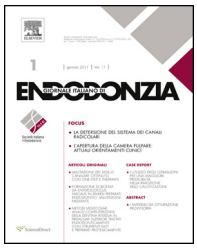

ORIGINAL ARTICLE/ARTICOLO ORIGINALE

Upper central incisors with periapical lesions treated with two integrated endodontic systems: a six-month randomized controlled trial

Incisivi centrali superiori con lesione periapicale trattati con due sistemi endodontici integrati: trial clinico controllato randomizzato a sei mesi

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KEYWORDS
Periapical lesion;
Integrated endodontic techniques;
Carrier based systems;
Healing.

Abstract
Aim: To assess preliminarily the success rate of the root canal treatment with two integrated shaping and filling systems of upper central incisors with chronic periapical pathosis.
Methodology: Sixty adult subjects with an untreated maxillary central incisor presenting a chronic periapical lesion smaller than 5 mm in diameter were recruited for the present study. The patients were randomly divided into two treatment groups: G1 (n = 30), Revo-S/One Step Obturator; G2 (n = 30) GTX/GTX Obturator. All root canal treatments were performed in a single session by the same operator. Sensitivity to palpation and percussion was registered at baseline

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and at the six-month recall. Radiographic healing was scored by two blind examiners according to a previously described scale. The absence of statistically significant differences in terms of baseline clinical parameters between the two groups was assessed by means of a Mann–Whitney test (age, apical gauging) and χ^2 test (sensitivity to percussion and palpation). The radiographic scores attributed to the two groups were compared with a Mann–Whitney test, while a χ^2 test served to compare the clinical data gathered after six months ($p < 0.05$).
Results: Baseline clinical parameters registered in the two groups were found to be comparable. All patients attended the six-month recall and all the teeth were referred to be negative to sensitivity, with the exemption of two subjects per group. The periapical lesions were scored as totally healed, partially healed and not healed in 43.4%, 53.3% and 3.3% of cases in G1 and in 43.3%, 50.0% and 6.7% of cases in G2. The differences between the groups were not significant.
Conclusions: Tough cases scored as incomplete healing should be further followed up, the present study attests that the two tested integrated shaping and filling systems are capable of high and comparable six-month success rate in upper central incisors with periapical pathosis.

PAROLE CHIAVE
Lesione periapicale;
Tecniche endodontiche integrate;
Sistemi carrier-based;
Guarigione.

Riassunto
Obiettivi: Valutare preliminarmente il tasso di successo del trattamento endodontico di incisivi centrali superiori con lesione periapicale eseguito con due sistemi integrati di strumentazione e otturazione.
Materiali e metodi: Sono stati reclutati 60 soggetti adulti con un incisivo mascellare centrale non trattato affetto da una lesione periapicale inferiore a 5 mm in diametro. I pazienti sono stati divisi casualmente in due gruppi di trattamento: G1 (n = 30), Revo-S/One Step Obturator; G2 (n = 30) GTX/GTX Obturator. Tutti i trattamenti endodontici sono stati eseguiti in singola seduta dal medesimo operatore. La dolorabilità alla palpazione e alla percussione è stata registrata al baseline e al controllo a sei mesi. Alla guarigione radiografica è stato attribuito un punteggio da due esaminatori estranei alla sperimentazione sulla base di una scala descritta in precedenza. L'assenza di differenze significative dei parametri di partenza tra i due gruppi è stata valutata con test Mann-Whitney (età, gauging apicale) e χ^2 (sensibilità a palpazione e percussione). I punteggi radiografici attribuiti ai due gruppi sono stati confrontati con un test di Mann-Whitney, mentre i dati clinici con test χ^2 ($p < 0,05$).
Risultati: I parametri clinici al baseline registrati nei due gruppi sono risultati paragonabili. Tutti i pazienti si sono presentati ai controlli a sei mesi, senza lamentare dolorabilità ai denti trattati, con l'eccezione di due soggetti per gruppo. Le lesioni periapicali sono state classificate come guarite, ridotte in dimensioni e non guarite rispettivamente nel 43,4%, 53,3% e 3,3% dei casi in G1 e nel 43,3%, 50,0% and 6,7% dei casi in G2. Le differenze tra i gruppi non erano statisticamente significative.
Conclusioni: Sebbene i casi classificati come guarigione parziale debbano essere ulteriormente seguiti nel tempo, il presente studio dimostra che i due sistemi integrati di strumentazione e otturazione sono capaci di tassi di successo elevati e tra loro simili per il trattamento della patologia periapicale di incisivi centrali superiori a 6 mesi.

Introduction

Remnants of necrotic pulp and microbial infection inside the endodontic space are known causes of common inflammatory odontogenic lesions, the most frequent being the periapical periodontitis and radicular cyst. For the root canal treatment to be successful in restoring the periapical health, the clinician should maximize his effort to chemo-mechanically remove the infected endodontic content and seal the root canal with an effective three-dimensional filling.

During the last years a modern trend of simplification of both shaping and filling techniques has arisen in endodontics. Several manufacturers are introducing on the market shaping systems with rotary files that require fewer steps than older systems.[1] Similarly, carrier-based systems allow for a single-step root canal filling without renouncing to the thermoplasticisation of the gutta-percha. It is known that the likelihood to introduce operative errors in the filling procedure increases with the number of steps, because micro-tomographic data attest that inexperienced operators can obtain better results with carrier-based techniques in comparison with the continuous wave of condensation.[2] Moreover, the correspondence in shape and size between the shaping and the filling instruments, which can be proposed as an integrated system, facilitates the clinician's tasks during the different phases of the endodontic treatment. Examples of

such systems are given by Revo-S (Micro-Mega, Besançon, France) and GTX rotary files (Dentsply Tulsa Dental Specialties, Tulsa, OK, USA), which have dedicated carrier-based obturators, to wit, the One-Step Obturator (CMS Dental ApS, Copenhagen, Denmark) and GTX Obturator (Dentsply Tulsa Dental Specialties). There is already some evidence attesting the sealing ability,[3] as well as the clinical effectiveness of these systems on different tooth types[1] as a valid alternative to traditional multi-step techniques.

The endodontic anatomy of the maxillary central incisor is known to seldom aberrate from the most frequent configuration of a generally wide and straight single canal. Even if upper anterior teeth with internal anatomy that markedly differs from the norm exist,[4,5] the almost invariable predominant form of the central incisor — i.e. a single root with a single canal — poses no peculiar difficulty for the treatment of this type of tooth in absence of case-specific hindrances. However, the apical diameter of these teeth is frequently wide so that the apical third of the root canal is not always easy to clean thoroughly and then seal tightly.

The aim of the present study is to test the null hypothesis that the six-month success rate of the root canal treatment of upper central incisors with chronic periapical pathosis does not differ when performed with two shaping and filling integrated systems.

Materials and methodology

This randomised controlled trial with two parallel groups design was prepared and reported following the CONSORT guidelines[6] and in agreement with the principles of the last update of the Helsinki Declaration. After being informed on the objective and the design of the study, all the patients assessed for eligibility gave their consent for the involvement in the study by signing a dedicated form.

Eligibility criteria

Consecutive male and female subjects who presented at the Dental Clinic of the University of Trieste between August 2014 and February 2015 were recruited for voluntary participation in the study. The inclusion criterion was the presence of an untreated maxillary central incisor with chronic periapical lesions smaller than 5 mm in diameter (measured on the periapical radiograph). The teeth were scheduled for single-session root canal treatment. Patients with physical or psychological disabilities, inability to understand instructions, severe systemic disorders (i.e. non-controlled diabetes, immunologic diseases, malignant neoplastic processes) were excluded from the trial. From a total of 70 subjects assessed for eligibility, 60 patients were enrolled in the present study. The phases of the trial (enrolment, allocation, follow-up, and analysis) are portrayed in Fig. 1. An independent operator, blind to the characteristics of the trial other than its design, generated the random sequence by stratified blocked randomization using a free simulation software.[7] The patients were unaware of the experimental group of assignment.

Interventions

The anamnestic data concerning the general and oral health were collected by interviewing the patients. A single operator examined the included patients wearing 4× magnifying loupes. The preoperative clinical signs were recorded,

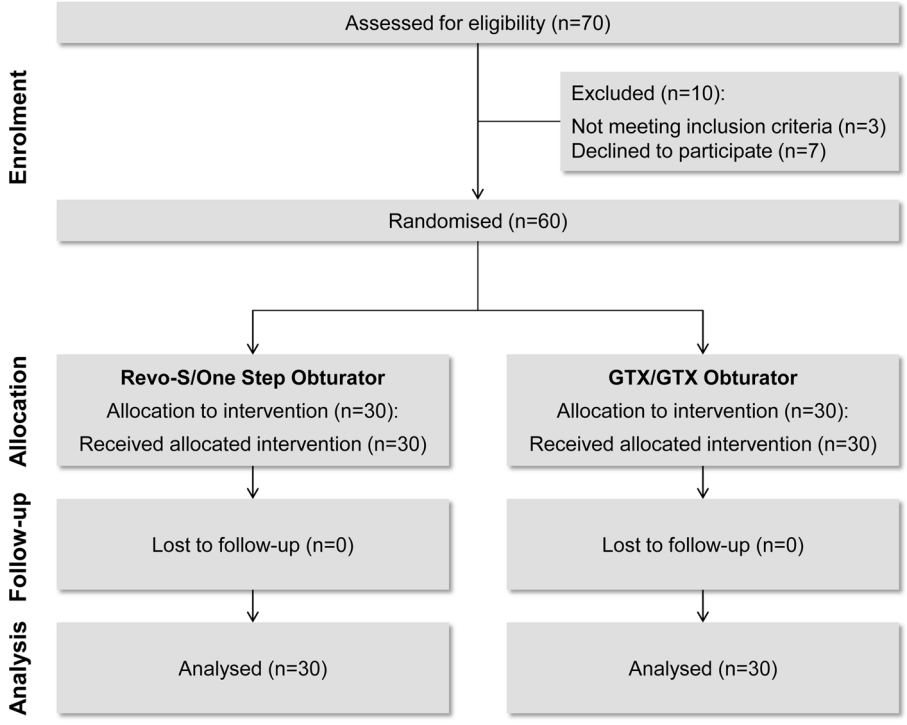

Figure 1 Flow diagram of the progress through the phases of the trial.

including tenderness to percussion or palpation of the buccal sulcus in the apical area.

A single experienced operator treated all enrolled patients. Before starting the root canal treatment, a rubber dam was positioned onto the designed tooth to obtain field isolation. If needed, a composite resin build-up restoration was made to achieve optimal marginal seal of the rubber dam. Coronal and apical patency was verified with a size 10 K file (Dentsply Maillefer, Ballaigues, Switzerland), which was connected to an electronic apex locator (Root ZX, Morita Co., Tokyo, Japan) for the determination of the electronic working length. All the other operative procedures other than the shaping and filling protocols were identical in the two groups. During instrumentation the canals were irrigated after each instrument with an endodontic syringe filled with 2.5 ml of 5.25% sodium hypochlorite (Niclor 5, Ogna, Muggiò, Italy).

For canal shaping, the rotary instruments were mounted on an endodontic handpiece connected to a dedicated motor (Tecnika Vision S, ATR, Pistoia, Italy) that was set in accordance with the indications suggested by the manufacturers. The canal shaping/filling protocols were as follows:

- Group 1 (G1, $n = 30$): the root canal was shaped making use of the standard sequence of rotary Revo-S instruments (Micro-Mega): SC 1 (25/.06), SC 2 (25/.04), and SU (25/.06). Afterwards, the apex was gauged with manual Ni-Ti files (Mity Turbo, JS Dental, Ridgefield, CT, USA) and accordingly enlarged with finishing files AS 30 (30/.06), AS 35 (35/.06) or AS 40 (40/.06). Manual refinement was performed if necessary. The root canal was dried with paper points and the canal walls were smeared with eugenol-free endodontic sealer (Sicura-Seal, Dentalica, Milano, Italy) using a sterile dry paper point. A carrier-based obturator of the One-Step Obturator system (CMS Dental ApS, Copenhagen, Denmark) chosen to match the apical preparation size was inserted into the One-Step Obturator Oven (CMS Dental ApS) to soften the outer gutta-percha and then introduced into the root canal 1 mm shorter of the working length. After 10 s, the handle of the obturator was cut at the orifice level with a dedicated bur mounted on a high speed handpiece.
- Group 2 (G2, $n = 30$): the root canal was shaped with GT Series X rotary files (Dentsply Tulsa Dental Specialties) in the order: 20/.04, 20/.06, 30/.04, 30/.06. The apical gauging was carried out as described in G1 and the apex was finished with .06 or 0.8 tapered GT Series X files. Canals were dried and their walls smeared with a eugenol-based sealer (Pulp Canal Sealer, SybronEndo, Orange, CA, USA). The filling procedure resembled that of G1 and was done with GT Series X Obturators and a Thermaprep oven (Dentsply Tulsa Dental Specialties).

Radiographic centering and examination

Customized Rinn XCP devices (Rinn Corp., Elgin, IL, USA) and a digital X-ray system (Vistascan Dental Perio, Dürr Dental AG, Bietigheim, Germany) were used throughout the study with a paralleling technique and a X-ray device (2200 Intraoral X Ray System, Kodak Dental Systems, Rochester, NY, USA) set at 70 kVp, 10 mA, and 0.20 s exposure time; the images were registered in ''Endo'' mode to enhance readability.[8] Radiographs were taken immediately after the conclusion of the root canal treatment (baseline) and at the six-month recall.

Two blind examiners with 19 and 23 years of clinical experience in endodontics extraneous to involved patients and study design were calibrated according to a previously described scale developed to score the healing of periapical lesions.[9] According to such scale, the follow-up radiographs were attributed to one of four categories (Fig. 2):

1. Healing: normal trabecular bone and physiological periodontal ligament width.
2. Improvement: decrease of the lesion size.
3. Failure: increase of lesion size or absence of changes from the initial status.
4. Unreadable radiograph.

Each follow-up radiograph was scored in the course of two sessions of radiographic evaluation that took place immediately after the collection of the radiological images and after one month.[10]

Statistical analysis

Both the sensitivity to percussion and palpation and the radiographic score were considered main outcome measures of the present trial. The Statistical Package for Social Sciences v. 15 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis of gathered data. The comparability of baseline parameters of the two groups was tested by means of a Mann—Whitney (age, apical diameter) and a χ^2 test (sensitivity to percussion and palpation). The differences between the groups in terms of radiographic score and clinical examination parameters (percussion and palpation) were assessed with the Mann—Whitney and χ^2 test, respectively. The level of intra- and inter-observer agreement of the rating of radiographic healing was evaluated with kappa statistics with quadratic weighting. The imputed relative distances between the ordinal categories served as basis for weighting: healing-improvement, 1; improvement-failure, 2.

Results

Table 1 summarizes the baseline variables, the sensitivity to percussion and palpation recorded at the six-month control as well as the worst radiographic scores attributed by the blind examiners. The two groups were found to be comparable at baseline, because they did not differ significantly in terms of age, apical diameter, and tenderness to percussion or palpation. No drop-outs or withdrawals occurred, with the totality of the patients enrolled in the present study attending the control visit. The radiographic healing scores followed a similar trend in the two groups. Both in G1 and G2, a substantial portion of subjects (≈43%) was totally healed after six months, while about half of the patients were classified as partially healed. There was no change or increase in size of the periapical lesion on the control radiographs of one patient in G1 and two patients in G2, who were also presenting symptoms and were classified as failures. As to the recall clinical examination, there was a patient in G1 reporting symptoms but classified as radiographically improved. All the other subjects were symptom-free. The statistical analysis did not point out significant difference between the two groups in any of the considered clinical or radiographic parameter.

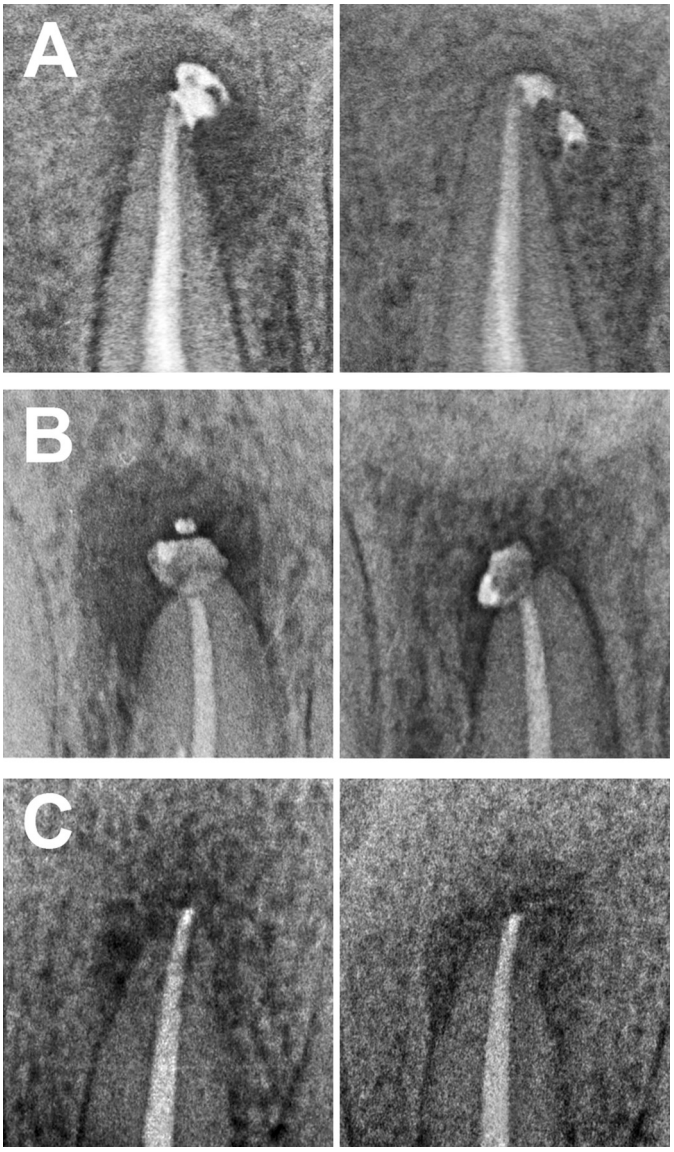

Figure 2 Representative radiographic appearance of the apical area of the three scores at baseline and recall: (A) healing, complete bone regeneration around the apex; (B) improvement, lesion reduced in size; and (C) failure, increase of lesion size or absence of changes from the initial status.

Both the intra- and inter-observer agreement rates of radiographic healing scores were excellent. The kappa values of intra-observer reliability ranged from 87% CI [68; 100] (observer A) to 92% CI [76; 100] (observer B), those of inter-observer reliability from 89% CI [70; 100] (second session) to 91% CI [74; 100] (first session). Discordance concerned only differences in classification between total and partial healing, whereas the evaluation of the cases considered radiological failures was consistent in time and between observers.

Discussion

Our results show that six months can be a sufficient follow-up time to observe complete radiographic healing of endodontically treated maxillary central incisors with a periapical lesion smaller than 5 mm in diameter. There are few studies that follow up endodontically treated teeth with periapical pathosis to monitor their radiographic healing. Murphy et al. had already reported complete healing rates similar to that of the present study after three months, presenting also six-month success rates around 60%.[11] Conversely, Peters and Wesselink observed markedly inferior healing rates in the same follow-up periods.[12] Such a variety of findings may be explained by the differences in terms of type of study, operators, techniques and characteristics of the lesions. For instance, Murphy analysed conventional film radiographies, which are known to be less sensitive than filtered digital radiographies.[8] Furthermore, the latter authors made use of 2% sodium hypochlorite as root canal irrigating solution,[12] when it is known that more concentrated solutions are needed for improve the irrigant antibacterial activity and dissolution power.[13] The fact remains that the findings of the present study are promising, since most of the lesions not totally healed after six months were found to be partially resorbed. It is conceivable that a complete healing of the

Table 1 Anamnestic variables, operative data, clinical and radiographic parameters registered at baseline and after six months: comparison between groups.

	Age (y)	Apical diameter (mm)	Baseline				Six-month recall				Radiographic score (%)			
			Vertical percussion test (%)		Palpation test (%)		Vertical percussion test (%)		Palpation test (%)		1	2	3	4
			+	−	+	−	+	−	+	−				
G1 $n = 30$	46.3 ± 19.4	0.38 ± 0.06	6.7	93.3	6.7	93.3	6.7	93.3	6.7	93.3	43.4	53.3	3.3	0
G2 $n = 30$	50.8 ± 19.6	0.39 ± 0.05	3.3	96.7	10.0	90.0	3.3	96.7	6.7	93.3	43.3	50.0	6.7	0
Diff.	$p = 0.340$	$p = 0.313$	$p = 0.554$		$p = 0.640$		$p = 0.554$		$p = 1.000$		$p = 0.887$			

Diff., statistical significance of difference between groups.

majority of these lesions will occur in the following six months.

The success rate of the endodontic treatment has been matter of study of a host of primary and secondary research, but its values are characterized by pronounced variability.[14–18] The root canal treatment is reported to be successful in a percentage of cases that ranges between 75% and 97%.[14,16,19] However, another source of variability is constituted by the difference of the types of studies, and, most importantly, by the kind of patients being recruited and treated. In fact, some studies do not distinguish between teeth with a healthy periapical status and those with a periodontal lesion. This fact considerably afflicts the reliability of the information that can be drawn from the reviews that do not distinguish such publications.[20] In agreement with this statement, a well-designed study demonstrated that the success rate of endodontic treatments carried out with Ni-Ti rotary files and Thermafil obturation may drop from 94% to 48% in case of periapical lesion.[21] Accordingly, a systematic review[14] reported that the presence of periapical radiolucency can worsen the prognosis of the root canal treatment by lowering the success rate as much as 8–13%.

The scale that has most frequently been used for determination of success is probably the periapical index (PAI)[22]; nonetheless, this index has been criticized in the past. The appropriateness of a general use of PAI for all teeth has been questioned, as it was developed on radiographic and histological findings of maxillary incisors.[20] The presence of a thick cortical plate or an unfavourable position of the root tip in relation to the cortex might limit the reliability of a radiographic assessment using PAI.[20] In the present study, the *a posteriori* outcome of the kappa statistics attested that adopting the scale described by Katebzadeh[9] was a good choice for the effective staging of the healing process of periapical lesions. Unlike PAI, which contemplates several classes with interpretable distinction, this scale was specifically formulated to classify an existing periapical lesion as disappeared, reduced in size, or unchanged/increased. These classes are easily understandable and clearly defined. Supported by the intrinsic simplicity of the scale, the radiographic assessment of the periapical changes of central maxillary incisors was a relatively easy task for the evaluators, almost free from the possibility of mistakes deriving from anatomical noise or other interferences. In this type of teeth, the customization of the film holder with a simple putty silicone registration assures sufficient repeatability of the radiographic image characteristics at different time points. This approach allows for a reliable assessment of the changes in size of a periapical lesion, even without making use of more complex and time-consuming techniques, like digital subtraction radiography.[1]

System-specific predefined operative protocols are suggested by the manufacturers in order to simplify the clinical practice and to reduce the influence of the operator. The two tested systems were chosen because they are modern techniques proposed as integrated combination of shaping and filling instruments. Specifically, the two series of Ni-Ti rotary files are manufactured by following present-day principles and the carrier-based obturators are similar in concept and materials to the Thermafil system, whose sealing ability is well-established.[23,24] GT series X files are the improved generation of the former GT. According to the manufacturer, the new M-Wire alloy that constitutes these new files enhances their mechanical properties. The manufacturer also claims that the new cross-section design, together with the coil angulation and variable radial planes, provides better cutting ability. These theoretical advantages are still discussed in literature. According to the findings of some studies, the new instruments are not characterized by improved resistance to cyclic fatigue[25] and torsional stress.[26] On the contrary, other studies reported significant advantages associated with GT series X files, such as increased resistance to flection,[27] resistance to torsion[28] and cyclic fatigue.[29]

With regard to the second tested file system, the triangular section of Revo-S files is asymmetric and has three cutting edges that correspond to the three different radii of the cross-section. Once the instrument has started rotating inside the canal, its particular shape would determine a vibrating snake-like motion, which is theoretically beneficial to the transportation of dentine debris out of the root canal. A limited number of articles have been produced on these instruments. There is some evidence attesting that Revo-S files tend to cause fewer dentinal microcracks than HERO Shaper (Micro-Mega), Twisted File (SybronEndo) and ProTaper rotary instruments (Dentsply Maillefer).[30] Other researchers found that, like many other Ni-Ti systems, Revo-S files can effectively shape the root canal, maintaining the preparation centred to the original endodontic anatomy, even in curved

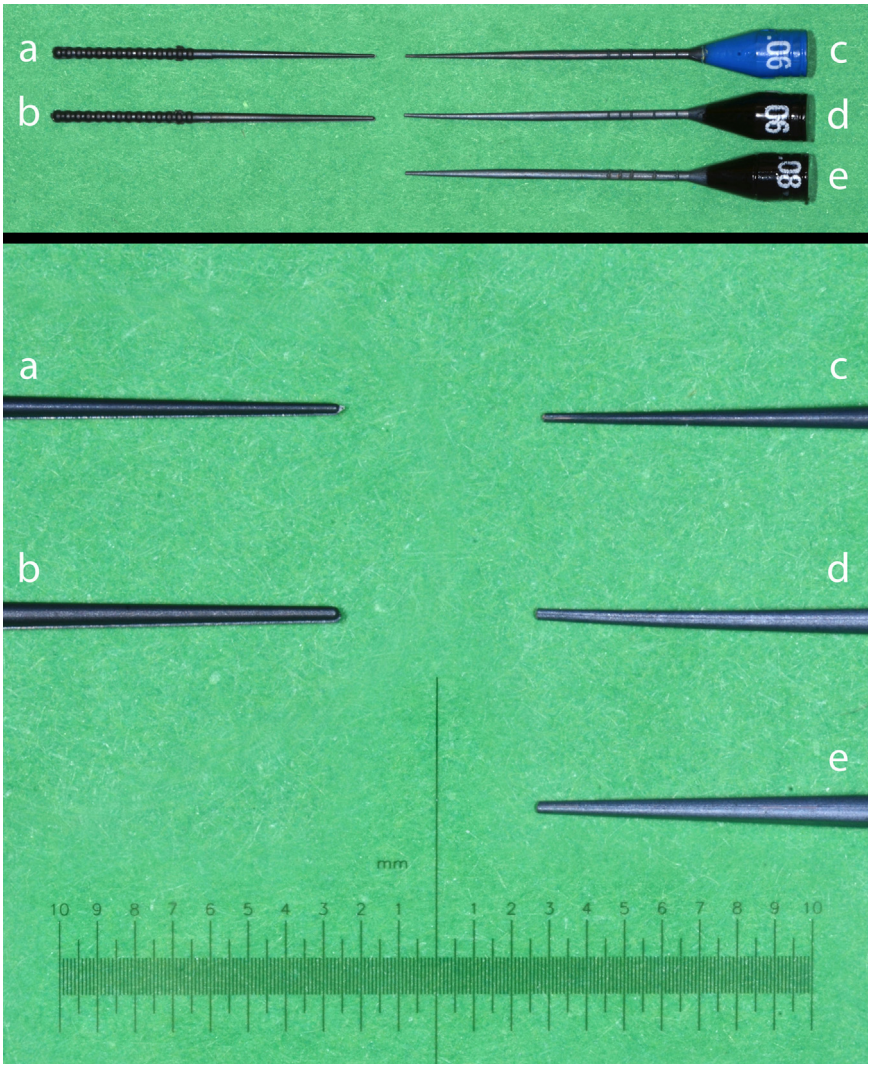

Figure 3 Microphotographs of carriers of different sizes belonging to the obturator systems used in the present study. The carriers have been deprived of the gutta-percha coating to measure apical diameter and taper. (a) Size 30 One Step Obturator; (b) size 40 One step Obturator; (c) size 30/.06 GTX Obturator; (d) size 40/.06 GTX Obturator; and (e) size 40/.08 GTX Obturator.

canals.[31] Another recent article demonstrated that they extrude a limited amount of apical debris, which was comparable to manual instrumentation.[32]

One aspect that, to the best of our knowledge, has been not taken into account by researchers is the influence of the shape of the carrier. In particular, it is unknown whether a carrier that exactly matches the shape of the rotary instruments actually brings advantage to the endodontic seal and, more importantly, to the clinical effectiveness of the treatment. Even if our study was not designed to address this specific issue, it preliminarily suggests that the influence of a strict shape correspondence between the rotary instruments and the carrier might not be necessarily relevant. Since information regarding the shape of the carrier was not available, we checked the dimensions and taper of the carriers via microscopic measurements, as portrayed in Fig. 3. We observed that One Step Obturators differ only in terms of tip diameter and are manufactured with unvarying taper (≈3%), while GTX Obturators are offered in different combinations of taper and tip diameter to match the relative rotary finishing file. These considerations lay the basis for future investigations.

In light of all the aforementioned advantages that characterise the two integrated systems and of the positive findings of the present study, it can be affirmed that both GTX and Revo-S instruments and their respective obturators perform well in the clinical setting, at least for the treatment of maxillary central incisors with periapical lesion.

Conclusions

The use of the integrated shaping and filling systems tested in the present trial led to a high preliminary success rate, which was similar in the two experimental groups. The correspondence in shape between the instruments of the shaping and filling techniques — like the case of the two tested systems — seems to be an effective and fast solution for the treatment of maxillary central incisors, even in case of periapical lesion.

Patients classified as partially healed after six months should be further followed-up.

Conflict of interest

The authors have no conflict of interest to declare.

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